PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

18

Substitute for form 1449A/PTO

1

	Complete if Known					
Application Number	10/787,417					
Filing Date	27 February 2004					
First Named Inventor	Chien-Hsuan HAN					
Art Unit	1615					
Examiner Name	UNASSIGNED					
Attorney Docket Number	49393-00004					

			U.S. PA	TENT DOCUMENTS	
Examiner	Cite	Document Number	Publication Date	Name of Patentee or Applicant	Pages, Columns, Lines, Where Relevant
nitials*	No.1	Number-Kind Code ² (if known)	MM-DD-YYYY	of Cited Document	Passages or Relevant Figures Appear
/SM/	A1	4,021,555	05/03/1977	SEYFRIED ET AL.	
	A2	4,160,020	07/03/1979	AYER ET AL.	
/SM/	A3	4,424,235	01/03/1984	SHETH ET AL.	
/SIM/	A4	4,839,177	06/13/1989	COLOMBO ET AL.	
,/ŞM/	A5	4,900,755	02/13/1990	DEMPSKI ET AL.	
12MI	A6	5,188,840	02/23/1993	IIDA ET AL.	
ר ייייי זועוכ	A7	5,446,194	08/29/1995	BÄCKSTRÖM ET AL.	
/SM/	A8	5,652,271	07/29/1997	HARRIS ET AL.	
/SM/	A9	5,738,874	04/14/1998	CONTE ET AL.	
	A10	6,238,699 B1	05/29/2001	RUBIN	·
	A11	6,294,200 B1	09/25/2001	CONTE ET AL.	
78W.	A12	6,500,867 B1	12/31/2002	VIRKKI ET ÅL.	
	A13	6,372,254 B1	04/16/2002	TING ET AL.	
/SM/	A14	2003/0224045 A1	12/04/2003	HAN ET AL.	
	A15	2003/0228360 A1	12/11/2003	HAN ET AL.	

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т ⁶		
/SM/	A16	WO 99/17745 A1	04/15/1999	CHIESI FARMACEUTICI S.P.A.				

Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.usplo.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ³ Kind of document by the appropriate symbols as Indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
/SM/	A17	STOCCHI ET AL., "COMPARISON BETWEEN A FAST AND A SLOW RELEASE PREPARATION OF LEVODOPA AND A COMBINATION OF THE TWO; A CLINICAL AND PHARMACOKINETIC STUDY", CLINICAL NEUROPHARMACOLOGY, Vol. 17, No. 1, pp. 38-44."				
/SM/	A18	STOCCHI ET AL., "CLINICAL EFFICACY OF SINGLE MORNING DOSES OF DIFFERENT LEVODOPA FORMULATIONS", CLINICAL NEUROPHARMACOLOGY, Vol. 17, Supp. 3, pp. S16-S20.				
/SM/	A19	HARDER ET AL., "CONCENTRATION-EFFECT RELATIONSHIP OF LEVODOPA IN PATIENTS WITH PARKINSON'S DISEASE AFTER ORAL ADMINISTRATION OF AN IMMEDIATE RELEASE AND A CONTROLLED RELEASE FORMULATION", Br. J. CLIN. PHARMAC., 1995; 39, pp.39-44.				

Examiner Signature	/Snigdha Maewall/	Date Considered	05/09/2007

^{*}EXAMINER: Initial If reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached.

Sul	bstitute for form 1449A/PTC	,		Complete if Known		
-				Application Number	10/787,417	
11	NFORMATIO	N DIS	SCLOSURE	Filing Date	27 February 2004	
5	STATEMENT	BY A	PPLICANT	First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many sheets as necessary)			Examiner Name	UNASSIGNED	
Sheet	2	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	
Examiner Initials	Cite No.1	item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T2
	A20	FASSIHI ET AL., "MULTIPLE-LAYER, DIRECT-COMPRESSION, CONTROLLED-RELEASE SYSTEM: IN	
/SM/		VITRO AND IN VIVO EVALUATION", JOURNAL OF PHARMACEUTICAL SCIENCES, Vol. 82, No. 7, JULY 1993, Pp. 750-754.	
	A21	GHIKA ET AL., "CLINICAL EFFICACY AND TOLERABILITY OF A NEW LEVODOPA/BENSERAZIDE DUAL-	
/SM/		RELEASE FORMULATION IN PARKINSONIAN PATIENTS", CLINICAL NEUROPHARMACOLOGY, Vol. 20, No. 2, pp. 130-139.	
	A22	GASSER ET AL., "COMPARATIVE SINGLE- AND MULTIPLE-DOSE PHARMACOKINETICS OF LEVODOPA	
/SM/	1	AND 3-O-METHYLDOPA FOLLOWING A NEW DUAL-RELEASE AND A CONVENTIONAL SLOW-RELEASE	
/ () ()		FORMULATION OF LEVODOPA AND BENSERAZIDE IN HEALTHY SUBJECTS", EUROPEAN JOURNAL OF	
/SM/		PHARMACEUTICS AND BIOPHARMACEUTICS 46 (1998), PP. 223-228.	Ļ
/SM/	A23	BORGES, "TOLCAPONE-RELATED LIVER DYSFUNCTION: IMPLICATIONS FOR USE IN PARKINSON'S	
701117	101	DISEASE THERAPY", DRUG SAFETY 2003, 26(11), PP. 743-747.	⊢
IONAL	A24	RAJPUT ET AL., "HUMAN BRAIN DOPAMINE METABOLISM IN LEVODOPA-INDUCED DYSKINESIA AND	
/SM/	105	WEARING OFF", PARKINSONISM AND RELATED DISORDERS, 10 (2004), PGS. 221-226.	┡
/SM/	A25	AHLSKOG ET AL., "CONTROLLED-RELEASE SINEMET (CR-4): A DOUBLE-BLIND CROSSOVER STUDY IN PATIENTS WITH FLUCTUATING PARKINSON'S DISEASE", MAYO CLINIC PROC, VOL. 63, SEPTEMBER	1
/SIVI/		1998, PP. 876-886.	Į
100.01	A26	ALMEIDA ET AL., "PHARMACOKINETIC-PHARMACODYNAMIC INTERACTION BETWEEN BIA 3-202, A	┢
/SM/	720	NOVEL COMT INHIBITOR AND LEVODOPA/CARBIDOPA", CLIN. NEUROPHARMACOL, Vol. 27, No. 1,	
		JANUARY-FEBRUARY 2004, PP. 17-24.	l
/SM/	A27	ANDERSON ET AL., "TRIAL OF SINEMET CR-4 IN PATIENTS WITH PARKINSON'S DISEASE", NEW	T
19111		ZEALAND MEDICAL JOURNAL, 11 MARCH 1992, PP. 81-82.	
10141	A28	BARTHOLINI ET AL., "DECARBOXYLASE INHIBITORS", PHARMAC. THERAP. B 1975, Vol. 1, No. 3, PP.	
/SM/		407-421.	
	A29	PAREJA ET AL., "CARBIDOPA DOSAGE MODIFIES L-DOPA INDUCED SIDE EFFECTS AND BLOOD LEVELS	Γ
/SM/		OF L-DOPA AND OTHER AMINO ACIDS IN ADVANCED PARKINSONISM", ACTA NEUROL SCAND., 1985,	1
		72:506-511.	L
/SM/	A30	BIANCHINE, "THE PHARMACIST", NEUROPHARMACOLOGY II, AUGUST 25, 1971, p. 231.	L
/SM/	A31	BLOCK ET AL., "COMPARISON OF IMMEDIATE RELEASE AND CONTROLLED-RELEASE	1
		CARBIDOPA/LEVODOPA IN PARKINSON'S DISEASE", EUROPEAN NEUROLOGY, 1997, 37:23-27.	L
-/SM/-	A32	BLUMENTHAL, NEUROLOGY, 43, 2729, DECEMBER 1993.	╀
/SM/	A33	BULLING, "CONTROLLED RELEASE LEVODOPA/CARBIDOPA (SINEMET CR4) IN PARKINSON DISEASE -	
	A34	AN OPEN EVALUATION OF EFFICACY AND SAFETY", AUST NZJ MED, 1991, 21:397-400. BURKHARD ET AL., "STRUCTURAL INSIGHT INTO PARKINSON'S DISEASE TREATMENT FROM DRUG-	⊢
101.41	A34	INHIBITED DOPA DECARBOXYLASE", NATURE STRUCTURAL BIOLOGY, VOL. 8, NO. 11, NOVEMBER	l
/SM/		2001, PP. 963-967.	Ì
	A35	BUSH ET AL., "AN OPEN MULTICENTER LONG-TERM TREATMENT EVALUATION OF SINEMET CR4",	╁
/SM/	733	NEUROLOGY, 1989 (39 SUPP 2), PP. 101-105.	
	A36	CAPILDEO, "IMPLICATIONS OF THE 5-YEAR CR FIRST TRIAL", THE AMERICAN ACADEMY OF	1
/SM/		NEUROLOGY, JUNE 1998, 50 (SUPP 6), PP. S15-S17.	l

Examiner	/Snigdha Maewall/	Date	05/09/2007
Signature	Portiguria Macwalli	Considered	03/03/2007

^{*}EXAMINER: initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached.

Subs	stitute for form 1449A/P	TO		Complete if Known		
0000				Application Number	10/787,417	
IN	IFORMATIC	ON DIS	CLOSURE	Filing Date	27 February 2004	
S	TATEMEN1	ΓBY AF	PPLICANT	First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many	sheets as ne	ecessary)	Examiner Name	UNASSIGNED	
Sheet	3	of	18	Attorney Docket Number	49393-00004	
		1 .1		1	I	

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	т—
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/SM	A37	CEDARBAUM ET AL., "CONTROLLED-RELEASE LEVODOPA/CARBIDOPA II SINEMET CR4 TREATMENT OF RESPONSE FLUCTUATIONS IN PARKINSON'S DISEASE", NEUROLOGY 37, OCTOBER 1987, PP. 1607-1612.	
/SM/	A38	CEDARBAUM ET AL., "A DOUBLE-BLIND CROSSOVER COMPARISON OF SINEMET CR4 AND STANDARD SINEMET 25/100 IN PATIENTS WITH PARKINSON'S DISEASE AND FLUCTUATING MOTOR PERFORMANCE", JOURNAL OF NEUROLOGY, NEUROSURGERY AND PSYCHIATRY, 1989, 52:207-212.	
/SM/	A39	CEDARBAUM ET AL., "Results of Long-Term Treatment with Controlled Release Levodopa/Carbidopa (Sinemet CR4)", JOURNAL OF NEURAL TRANSMISSION, 1990, 2:205-213.	
/SM/	A40	CEDARBAUM, "Stability of Levopdopa/Carbidopa Solutions", "MOVEMENT DISORDERS, Vol. 12, No. 4, 1997, pp. 625.	
/SM/	A41	DA PRADA ET AL., "Inhibition of Decarboxylase and Levels of Dopa and 3-0-Methyldopa: A Comparitive Study of Benserazide Versus Carbidopa in Rodents and of Madopar Standard Versus Madopar HBS in Volunteers", EURO NEUROL., 27 SUPPL. 1, PP. 9-20 (1987).	
/SM/	A42	DELEU ET AL., "Controlled-Release Carbidopa/Levodopa (CR) in Parkinsonian Patients with Response Fluctuations on Standard Levodopa Treatment: Clinical and Pharmokinetic Observations", Neurology, November 1989, 39 Supp. 2: 88-92.	
/SM/	A43	DEMPSKI ET AL., "PHARMACEUTICAL DESIGN AND DEVELOPMENT OF A SINEMET CONTROLLED- RELEASE FORMULATION", NEUROLOGY, 1989, 39 SUPP. 2:20-24.	
/SM/	A44	FELDMAN ET AL., "DOUBLE-BLIND COMPARISON OF STANDARD SINEMET AND SINEMET CR IN PATIENTS WITH MILD-TO-MODERATE PARKINSON'S DISEASE", NEUROLOGY, 1989, 39 SUPP. 2:96-105.	
/SM/	A45	FOWLER ET AL., "CONTINUOUS DUODENAL INFUSIONS OF LEVODOPA", JOURNAL OF NEUROSCIENCE NURSING, OCTOBER 1993, Vol. 25, No. 5, pp. 317-319.	
/SM/	A46	FRIEDMAN ET AL., "AN OPEN TRIAL OF CONTROLLED RELEASE CARBIDOPA/L-DOPA (SINEMET CR) FOR THE TREATMENT OF MILD-TO MODERATE PARKINSON'S DISEASE", CLIICAL NEUROPHARMACOLOGY, Vol. 12, No. 3, pp. 220-223.	
/SM/	A47	GOETZ ET AL., "CONTROLLED RELEASE SINEMET", NEUROLOGY, 37, SEPTEMBER 1987, PP. 1567-1568.	
/SM/	A48	GOETZ ET AL., "PARKINSON'S DISEASE AND MOTOR FLUCTUATIONS: LONG-ACTING CARBIDOPA/LEVODOPA (CR-4-SINEMET)", NEUROLOGY, 37, MAY 1987, PP. 875-878.	
/SM/	A49	GOETZ ET AL., "LIMITS OF PREDICTIVE FACTORS IN EARLY PARKINSON'S DISEASE", NEUROLOGY, 37, SUPP. 1, MARCH 1987, Pp. 270 (pp. 367).	
/SM/	A50	GOETZ ET AL., "CONTROLLED-RELEASE CARBIDOPA/LEVODOPA (CR4-SINEMET) IN PARKINSON'S DISEASE PATIENTS WITH AND WITHOUT MOTOR FLUCTUATIONS", NEUROLOGY, 38, JULY 1988, PP. 1143-1146.	
/SM/	A51	GOETZ ET AL., "Development and Progression of Motor Fluctuations and Side Effects in Parkinson's Disease, Comparison of Sinemet CR versus Carbidopa/Levodopa", NEUROLOGY, 39, NOVEMBER 1988 (SUPPL. 2), PP. 63-66.	
/SM/	A52	HAUSER ET AL., "TIME COURSE OF LOSS OF BENEFIT FOLLOWING WITHDRAWAL OFLEVODOPA/CARBIDOPA AND BROMOCRIPTINE IN EARLY PARKINSON'S DISEASE", MOVEMENT DISORDERS, Vol. 15, No. 3, 2000, pp. 485-489.	

Examiner	/Snigdha Maewall/	Date	05/09/2007
Signature	/Orliguria iviaewali/	Considered	03/09/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Sul	bstitute for form 1449A/F	PTO		Complete if Known		
				Application Number	10/787,417	
11	NFORMATIO	ON DIS	CLOSURE	Filing Date	27 February 2004	
l s	STATEMEN ^T	T BY A	PPLICANT	First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many	/ sheets as no	ecessary)	Examiner Name	UNASSIGNED	
Sheet	4	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	,
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/SM/	A53	HAUSER ET AL., "QUANTITATIVE DESCRIPTION OF LOSS OF CLINICAL BENEFIT FOLLOWING FOLLOWING WITHDRAWAL OF LEVODOPA-CARBIDOPA AND BROMOCRIPTINE IN EARLY PARKINSON'S DISEASE", MOVEMENT DISORDERS, Vol. 17, No. 5, 2002, pp. 961-968.	
/SM/	A54	HOEHM, "Increased Dosage of Carbidopa in Patients with Parkinson's Disease Receiving Low Doses of Levodopa", Arch Neurol, Vol. 37, March 1980, pp. 146-149.	
/SM/	A55	HUTTON ET AL., "CONTROLLED-RELEASE CARBIDOPA/LEVODOPA IN THE TREATMENT OF PARKINSONISM", CLINICAL NEUROPHARMACOLOGY, VOL. 7, No. 2, 1984, pp. 135-139.	
/SM/	A56	HUTTON ET AL., "TREATMENT OF CHRONIC PARKINSON'S DISEASE WITH CONTROLLED-RELEASE CARBIDOPA/LEVODOPA", ARCH NEUROL, Vol. 45, AUGUST 1988, PP. 861-864.	
/SM/	A57	HUTTON ET AL., "A DOUBLE-BLIND CROSSOVER STUDY OF CONTROLLED-RELEASE CARBIDOPA/LEVODOPA (CR-4) AND SINEMET IN ADVANCED PARKINSON'S DISEASE", NEUROLOGY 38 (SUPP 1), MARCH 1988, P. 329 (PP. 549).	
/SM/	A58	HUTTON ET AL., "MULTICENTER CONTROLLED STUDY OF SINEMET CR4 VERSUS SINEMET (25/100) IN ADVANCED PARKINSON'S DISEASE", NEUROLOGY, 39 (SUPP. 2), NOVEMBER 1989, PP. 67-73.	
/SM/	A59	HUTTON ET AL., "LONG-TERM EVALUATION OF SINEMET CR IN PARKINSONIAN PATIENTS WITH MOTOR FLUCTUATIONS", CAN. J. NEUROL. SCI., NOVEMBER 1991, 18:467-471.	
/SM/		HUTTON ET AL., "LONG-ACTING CARBIDOPA/LEVODOPA IN THE MANAGEMENT OF MODERATE AND ADVANCED PARKINSON'S DISEASE", NEUROLOGY, 42 (SUPP 1), JANUARY 1992, PP. 51-60.	
/SM/	A61	JAFFE, "CLINICAL STUDIES OF CARBIDOPA AND L-DOPA IN THE TREATMENT OF PARKINSON'S DISEASE", ADVANCES IN NEUROLOGY, Vol. 2, 1973, Pp. 161-172.	
/SM/	A62	JANKOVIC ET AL., "COMPARISON OF SINEMET CR4 AND STANDARD SINEMET: DOUBLE BLIND AND LONG-TERM OPEN TRIAL IN PARKINSONIAN PATIENTS WITH FLUCTUATIONS", MOVEMENT DISORDERS, Vol. 4, No. 4, 1989, pp. 303-309.	
/SM/	A63	JOSEPH et al., "Adverse Reactions to Controlled Release Levodopa/Carbidopa in Older Persons: Case Reports", JAGS, January 1995, Vol. 43, No. 1, pp. 47-50.	
/SM/	A64	KOLLER ET AL., "TREATING MOTOR FLUCTUATIONS WITH CONTROLLED-RELEASE LEVODOPA PREPARATIONS", NEUROLOGY, JULY 1994, 44 (SUPP 6), S23-S28.	
/SM/	A65	KOLLER ET AL., "IMMEDIATE-RELEASE AND CONTROLLED-RELEASE CARBIDOPA/LEVODOPA IN PD: A 5-YEAR RANDOMIZED MULTICENTER STUDY", NEUROLOGY, SEPTEMBER 1999, Vol. 53, pp. 1012-1019.	
/SM/	A66	KURTH ET AL., "USING LIQUID LEVODOPA IN THE TREATMENT OF PAPKINSON'S DISEASE", DRUGS & AGING, 10(5), MAY 1997, VOL. 10, NO. 5, PP. 332-340.	
/SM/	A67	LEIBOWITZ ET AL., "COMPARISON OF DOPA DECARBOXYLASE INHIBITOR (CARBIDOPA) COMBINED WITH LEVODOPA AND LEVODOPA ALONE ON THE CARDIOVASCULAR SYSTEM OF PATIENTS WITH PARKINSON'S DISEASE", NEUROLOGY, 25:917-921, OCTOBER 1975.	
/SM/	A68	LEWITT ET AL., "CONTROLLED-RELEASE CARBIDOPA/LEVODOPA (SINEMET 50/200 CR4): CLINICAL AND PHARMACOKINETIC STUDIES", NEUROLOGY, 39 (SUPP 2), NOVEMBER 1989, PP. 45-53.	

Examiner	/Snigdha Maewall/	Date	05/00/2007
Signature	3	Considered	05/09/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). Papplicant is to place a check mark here if English language Translation is attached.

Sut	Substitute for form 1449A/PTO			Complete if Known		
				Application Number	10/787,417	
11	NFORMATIC	N DI	SCLOSURE	Filing Date	27 February 2004	
S	STATEMENT	BY A	APPLICANT	First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many sheets as necessary)			Examiner Name	UNASSIGNED	
Sheet	5	of	18	Attomey Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/SM/	A69	LIEBERMAN et al., "Randomizized Double-Blind Crossover STudy of Sinemet-Controlled Release (CR4 50/200) versus Sinemet 25/100 in Parkinson's Disease", Euro Neurol., 1990, 30:75-78.	
/SM/	A70	LINAZASORO ET AL, "CONTROLLED RELEASE LEVODOPA IN PARKINSON'S DISEASE: INFLUENCE OF SELECTION CRITERIA AND CONVERSION RECOMMENDATIONS IN THE CLINICAL OUTCOME OF 450 PATIENTS", CLINICAL NEUROPHARMACOLOGY, 1999, Vol. 22, No. 2, pp. 74-79.	
/SM/	A71	MANYAM ET AL., "STANDARD CARBIDOPA-LEVODOPA VERSUS CONTROLLED-RELEASE CARBIDOPA- LEVODOPA IN PARKINSON'S DISEASE: A POSTMARK ANALYSIS", CLINICAL NEUROPHARMACOLOGY, 1999, Vol. 17, No. 2, pp. 128-137.	
/SM/	A72	MANYAM ET AL., "EVALUATION OF EQUIVALENT EFFICACY OF SINEMET AND SINEMET CR IN PATIENTS WITH PARKINSON'S DISEASE APPLYING LEVODOPA DOSAGE CONVERSION FORMULA", CLINICAL NEUROPHARMACOLOGY, 1999, Vol. 22, No. 1, pp. 33-39.	
/SM/	A73	MARK ET AL., "CONTROLLED-RELEASE CARBIDOPA-LEVODOPA (SINEMET) IN COMBINATION WITH STANDARD SINEMET IN ADVANCED PARKINSON'S DISEASE", ANNALS OF CLINICAL AND LABORATORY SCIENCE, VOL. 19, No. 2, 1989, pp. 101-106.	
/SM/	A74	MARK ET AL., "LONG-TERM EFFICACY OF CONTROLLED-RELEASE CARBIDOPA/LEVODOPA IN PATIENTS WITH PARKINSON'S DISEASE", ANNALS OF CLINICAL AND LABORATORY SCIENCE, Vol. 19, No. 6, 1989, Pp. 415-421.	
/SM/	A75	MESSIHA ET AL, "EFFECTS OF PERIPHERAL AROMATIC L-AMINO ACIDS DECARBOXYLASE INHIBITOR ON L- [2-14C]-3,4-DIHYDROXYPHENYLALANINE METABOLISM IN MAN", BIOCHEMICAL PHARMACOLOGY, 1972, Vol. 21, pp. 2144-2147.	
/SM/	A76	NAHATA ET AL., "DEVELOPMENT OF TWO STABLE ORAL SUSPENSIONS OF LEVODOPA-CARBIDOPA FOR CHILDREN WITH AMBLYOPIA", JOURNAL OF PEDIATRIC OPTHAMOLOGY "& STRABISMUS, Vol. 37, No. 6, Nov/Dec 2000.	
/SM/	A77	NUTT ET AL., "CLINICAL AND BIOCHEMICAL STUDIES WITH CONTROLLED-RELEASE CARBIDOPA/LEVODOPA", NEUROLOGY, SEPTEMBER 1986, 36:1206-1211.	
/SM/	A78	OLANOW ET AL., "AN OPEN MULTICENTER TRIAL OF SINEMET CR IN LEVODOPA-NAIVE PARKINSON'S DISEASE PATIENTS", CLINICAL NEUROPHARMACOLOGY, 1991, Vol. 14, No. 3, pp. 235-240.	
/SM/	A79	PAHWA ET AL., "CLINICAL EXPERIENCE WITH CONTROLLED-RELEASE CARBIDOPA/LEVODOPA IN PARKINSON'S DISEASE", NEUROLOGY, APRIL 1993, 43:677-681.	
/SM/	A80	PAHWA ET AL., "TREATMENT OF PARKINSON'S DISEASE IN CONTROLLED-RELEASE CARBIDOPA/L-DOPA", ADVANCES IN NEUROLOGY, Vol. 69, 1996, pp. 487-491.	
/SM/	A81	PAPPERT ET AL., "LEVODOPA STABILITY IN SOLUTION: TIME COURSE, ENVIRONMENTAL EFFECTS, AND PRACTICAL RECOMMENDATIONS FOR CLINICAL USE", MOVEMENT DISORDERS, Vol. 11, No. 1, 1996, pp. 24-26.	
/SM/	A82	PAPPERT ET AL., "CLINICAL/SCIENTIFIC NOTES: THE STABILITY OF CARBIDOPA IN SOLUTION", MOVEMENT DISORDERS, Vol. 12, No. 4, 1997, pp. 608-623.	

- 4				
i	Examiner	/Snigdha Maewall/	Date	05/09/2007
1	Signature	/Snigona iviaewaii/	Considered	00.00.200.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Oraw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002.OMB 0551-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449A/PTO 10/787,417 **Application Number** INFORMATION DISCLOSURE 27 February 2004 Filing Date STATEMENT BY APPLICANT Chien-Hsuan HAN First Named Inventor Art Unit 1615 (use as many sheets as necessary) **UNASSIGNED Examiner Name** 49393-00004 Sheet 6 of 18 **Attorney Docket Number**

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.'	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/SM/	A83	PFIEFFER ET AL., "SINEMET CR IN PARKINSON'S DISEASE", NEBRASKA MEDICAL JOURNAL, JANUARY 1991, PP. 8-10.	
/SM/		PINDER ET AL., "LEVODOPA AND DECARBOXYLASE INHIBITORS: A REVIEW OF THEIR CLINICAL PHARMACOLOGY AND USE IN THE TREATMENT OF PARKINSONISM", DRUGS (1976), 11:277-377	
/SM	A85	PORTER, "INHIBITORS OF AROMATIC AMINO ACID DECARBOXYLASE — THEIR BIOCHEMISTRY", ADVANCES IN NEUROLOGY, Vol. 2, 1973.	
/SM/	A86	RAFTOPOULOS ET AL., "SLOW INCREASE OF HOMOVANILLIC ACID IN CEREBROSPINAL FLUID AFTER LEVODOPA ADMINISTRATION", MOVEMENT DISORDERS, VOL. 11, NO. 1, 1996, PP. 59-62.	
/SM/	A87	RINNE ET AL., "TREATMENT OF EARLY PARKINSON'S DISEASE WITH CONTROLLED-RELEASE LEVODOPA PREPARATIONS", NEUROLOGY, 39 (SUPP 2), NOVEMBER 1989, PP. 78-81.	
/SM/	A88	RODNITZKY, "THE USE OF SINEMET CR IN THE MANAGEMENT OF MILD TO MODERATE PARKINSON'S DISEASE", NEUROLOGY, 42 (SUPP 1), JANUARY 1992, PP. 44-50.	
/SM/	A89	SAGE ET AL, "COMPARISON OF CONTROLLED-RELEASE SINEMET (CR4) AND STANDARD SINEMET (25 MG/100 MG) IN ADVANCED PARKINSON'S DISEASE: A DOUBLE-BLIND CROSSOVER STUDY", CLINICAL NEUROPHARMACOLOGY, Vol. 11, No. 2, 1988, pp. 174-179.	
/SM/	A90	SIMPSON ET AL., "DOUBLE-BLIND CARBIDOPA/LEVODOPA AND PLACEBO STUDY IN TARDIVE DYSKENESIA", JOURNAL OF CLINICAL PSYCHOPHARMACOLOGY, VOL. 8, No. 4, AUGUST. 1988.	
/SM/	A91	STOCCHI ET AL., "CLINICAL IMPLICATIONS OF SUSTAINED DOPAMINERGIC STIMULATION", CLINICAL NEUROPHARMACOLOGY, 1994, Vol. 17, Supp. 2, S7-S13.	
/SM/	A92	TOURTELLOTE ET AL., "INCREASED RATIO OF CARBIDOPA TO LEVODOPA IN TREATMENT OF PARKINSON'S DISEASE", ARCH NEUROL, VOL. 37, NOV. 1980, Pp. 723-726.	
/SM/	A93	TSUI ET AL., "DECREASED EFFICACY OF LEVODOPA WITH CARBIDOPA IN PARKINSONIAN PATIENTS AFTER ADRENAL-TO-CAUDATE IMPLANTS", NEUROLOGY, VOL. 40, MAY 1990, PP. 845-846.	
/SM/	A94	VAN HORN, "Immediate Release and Controlled-Release Carbidopa/Levodopa in PD: A 5- Year Randomized Multicenter Study", Neurology, Vol. 55, July 2000, pp. 156-157.	
/SM/	A95	WARD ET AL., "L-DOPA DECARBOXYLATION IN CHRONICALLY TREATED PATIENTS", NEUROLOGY, VOL. 34, FEBRUARY 1984, PP. 198-201.	
/SM/	A96	WILDING ET AL, "GASTROINTESTINAL TRANSIT OF SINEMET CR IN HEALTHY VOLUNTEERS", NEUROLOGY, 39 (SUPP. 2), 1989, PP. 53-59.	
/SM/	A97	WOLTERS ET AL., "CLINICAL EFFICACY OF SINEMET CR 50/200 VERSUS SINEMET 25/100 IN PATIENTS WITH FLUCTUATING PARKINSON'S DISEASE: AN OPEN, AND A DOUBLE-BLIND, DOUBLE-DUMMY, MULTICENTER TREATMENT EVALUATION", CLINICAL NEUROLOGY AND NEUROSURGERY, VOL. 94 (1992), PP. 205-211.	
/SM/	A98	WOLTERS ET AL., "SUPERIOR CLINICAL EFFICACY OF SINEMET CR 50/200 VERSUS SINEMET 25/100 IN PATIENTS WITH FLUCTUATING PARKINSON'S DISEASE: AN OPEN AND A DOUBLE-BLIND, DOUBLE-DUMMY, MULTICENTER TREATMENT", ADVANCES IN NEUROLOGY, Vol. 60, 1993, pp. 648-652.	
/SM/	A99	GERVASON ET AL., "REPRODUCIBILITY OF MOTOR EFFECTS INDUCED BY SUCCESSIVE SUBCUTANEOUS APOMORPHINE INJECTIONS IN PARKINSON'S DISEASE", CLINICAL NEUROPHARMACOLOGY, 1993, Vol. 16, No. 2, pp. 113-119.	

Examiner	/Snigdha Maewall/	Date	05/09/2007
Signature	Torrigaria maowani	Considered	03/09/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached.

Sul	Substitute for form 1449A/PTO			Complete if Known		
				Application Number	10/787,417	
- 11	VFORMATION	ON DISC	CLOSURE	Filing Date	27 February 2004	
9	STATEMEN'	T BY AP	PLICANT	First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many	sheets as nec	essary)	Examiner Name	UNASSIGNED	
Sheet	7	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/SM/	A100	WOLTERS ET AL., "INTERNATIONAL (NL-UK) DOUBLE-BLIND STUDY OF SINEMET CR AND STANDARD SINEMET (25/100) IN 170 PATIENTS WITH FLUCTUATING PARKINSON'S DISEASE", J. NEUROL., 243 (1996), PP. 235-240.	
/SM/	A101	BRAVI ET AL., "WEARING-OFF FLUCTUATIONS IN PARKINSON'S DISEASE: CONTRIBUTION OF POST SYNAPTIC MECHANISMS", ANNALS OF NEUROLOGY, JULY 1994, Vol. 36, NO. 1, pp. 27-31.	
/SM/	A102	DUBY ET AL., "INJECTED APOMORPHINE AND ORALLY ADMINISTERED LEVODOPA IN PARKINSONISM", ARCH. NEUROL., VOL. 27, DECEMBER 1972, Pp. 474-480.	
/SM/	A103	GANCHER ET AL, "PERIPHERAL PHARMACOKINETICS OF APOMORPHINE IN HUMANS", ANNALS OF NEUROLOGY, Vol. 26, No. 2, August 1989, pp. 232-238.	
/SM/	A104	GANCHER ET AL., "APOMORPHINE TOLERANCE IN PARKINSON'S DISEASE: LACK OF A DOSE EFFECT", CLINICAL NEUROPHARMACOLOGY, 1996, Vol. 19, No. 1, PP. 59-64.	
/SM/	A105	HUGHES ET AL., "SUBCUTANEOUS APOMORPHINE IN PARKINSON'S DISEASE: RESPONSIVE CHRONIC ADMINISTRATION FOR UP TO FIVE YEARS", MOVEMENT DISORDERS, 1993, Vol. 8, No. 2, Pp. 165-170.	
/SM/	A106	LLAU ET AL., "A STUDY OF DOPAMINERGIC SENSITIVITY IN PARKINSON'S DISEASE: COMPARISON IN 'DE NOVO' AND LEVODOPA-TREATED PATIENTS", CLINICAL NEUROPHARMACOLOGY, 1996, Vol. 19, NO. 5, PP. 420-427.	
/SM/	A107	MONTASTRUC ET AL., "SUBLINGUAL APOMORPHINE AND PARKINSON'S DISEASE: A CLINICAL AND PHARMACOKINETIC STUDY", CLINICAL PHARMACOLOGY, 1991, Vol. 14, No. 5, Pp. 432-437.	
/SM/	A108	MONTASTRUC ET AL, "SUBLINGUAL APOMORPHINE: A NEW PHARMACOLOGICAL APPROACH IN PARKINSON'S DISEASE?", JOURNAL OF NEURAL TRANSMISSION, 1995, 45 (SUPP), PP. 157-161.	
/SM/	A109	MONTASTRUC ET AL, "A STUDY OF TOLERANCE TO APOMORPHINE", BRITISH JOURNAL OF PHARMACOLOGY, 117 (1996), PP. 781-786.	
/SM/	A110	NEEF ET AL., "PHARMACOKINETIC-PHARMACODYNAMIC RELATIONSHIPS OF APOMORPHINE IN PATIENTS WITH PARKINSON'S DISEASE", CLIN. PHARMACOKINET, SEPTEMBER 1999, 37 (3), pp. 257-271.	
/SM/	A111	NICOLLE ET AL., "PHARMACOKINETICS OF APOMORPHINE IN PARKINSONIAN PATIENTS", FUNDAM CLIN PHARMACOL, 7, 1993, pp. 245-252.	
/SM/	A112	METMAN ET AL., "APOMORPHINE RESPONSES IN PARKINSON'S DISEASE AND THE PATHOGENESES OF MOTOR COMPLICATIONS", NEUROLOGY, 48 (1997), Pp. 369-372.	
/SM/	A113	DANIELCZYK, "TWENTY-FIVE YEARS OF AMANTADINE THERAPY IN PARKINSON'S DISEASE", JOURNAL OF NEURAL TRANSMISSION, 1995 (SUPP) 46, PP. 399-405.	
/SM/	A114	DEL DOTTO ET AL., "INTRAVENOUS AMANTADINE IMPROVES LEVODOPA-INDUCED DYSKINESIAS: AN ACUTE DOUBLE-BLIND PLACEBO-CONTROLLED STUDY", MOVEMENT DISORDERS (2001), Vol. 16, No. 3, pp. 515-520.	
/SM/	A115	ANDRINGA ET AL., "THE ALLEGED DOPAMINE D1 RECEPTOR AGAINST SKF 83959 IS A DOPAMINE D1 RECEPTOR ANTAGONIST IN PRIMATE CELLS AND INTERACTS WITH OTHER RECEPTORS", EUROPEAN JOURNAL OF PHARMACOLOGY, 1999, 364, pp. 33-41.	
/SM/	A116	ARAI ET AL., "COMBINED EFFECTS OF CABERGOLINE AND L-DOPA ON PARKINSONISM IN MPTP-TREATED CYNOMOLGUS MONKEYS", JOURNAL OF NEURAL TRANSMISSIONS (1996), 103, pp. 1307-1316.	

Examiner	/Snigdha Maewall/	Date	05/00/0007
Signature	70mgana Wacwall/	Considered	05/09/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

Sub	stitute for form 1449A/PTO				Complete if Known
				Application Number	10/787,417
11	NFORMATION	1 DI	SCLOSURE	Filing Date	27 February 2004
S	TATEMENT B	3Y /	APPLICANT	First Named Inventor	Chien-Hsuan HAN
				Art Unit	1615
	(use as many sh	eets as	necessary)	Examiner Name	UNASSIGNED
Sheet	8	of	18	Attorney Docket Number	49393-00004

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/SM/	A117	LUGINGER ET AL., "BENEFICIAL EFFECTS OF AMANTADINE ON L-DOPA-INDUCED DYSKINESIAS IN PARKINSON'S DISEASE", MOVEMENT DISORDERS, 2000, Vol. 15, No. 5, PP. 873-878.	
/SM/	A118	SNOW ET AL., "THE EFFECT OF AMANTADINE ON LEVODOPA-INDUCED DYSKINESIAS IN PARKINSON'S DISEASE: A DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY", CLINICAL NEUROPHARMACOLOGY, 2000, Vol. 23, NO. 2, Pp. 82-85.	
/SM/	A119	THOMAS ET AL., "DURATION OF AMANTADINE BENEFIT ON DYSKENSIA OF SEVERE PARKINSON'S DISEASE", J. NEUROL. NEUROSURG. PYSCHIATRY (2004), 75, PP. 141-143.	
/SM/	A120	METMAN ET AL., "AMANTADINE AS TREATMENT FOR DYSKINESIAS AND MOTOR FLUCTUATIONS IN PARKINSON'S DISEASE", NEUROLOGY (1998), 50, PP. 1323-1326.	
/SM/	A121	METMAN ET AL., "AMANTADINE FOR LEVODOPA-INDUCED DYSKINESIAS: A 1-YEAR FOLLOW UP STUDY", ARCH. NEUROL (1999), 56, 1383-1386.	
/SM/	A122	BIGLAN ET AL., "A REVIEW OF PRAMIPEXOLE AND IT'S CLINICAL UTILITY IN PARKINSON'S DISEASE", EXPERT OPINION PHARMACOTHERAPY (2002), 3(2), PP. 197-210.	
/SM/	A123	BONUCCELLI ET AL., "PERGOLIDE IN THE TREATMENT OF PATIENTS WITH EARLY AND ADVANCED PARKINSON'S DISEASE", CLINICAL NEUROPHARMACOLOGY (2002), Vol. 25, No. 1, Pp. 1-10.	
/SM/	A124	BREFEL ET AL., "EFFECT OF FOOD ON THE PHARMACOKINETICS OF ROPINIROLE IN PARKINSONIAN PATIENTS", BR. J. CLINICAL PHARMACOL. (1998), 45, PP. 412-415.	
/SM/	A125	DE YEBENES, "INTRODUCTION: PRAMIPEXOLE: A NOVEL DOPAMINE AGONIST FOR THE TREATMENT OF PARKINSON'S DISEASE", EUROPEAN JOURNAL OF NEUROLOGY SUPPLEMENT, SEPTEMBER 2000, 7 (SUPP. 1), PP. 1-2.	
/SM/	A126	ETMINAN ET AL., "INCREASED RISK OF SOMNOLENCE WITH THE NEW DOPAMINE AGONISTS IN PATIENTS WITH PARKINSON'S DISEASE: A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS", DRUG SAFETY (2001), 24 (11), pp. 863-868.	
/SM	A127	H. TAHAR ET AL., "SUSTAINED CABERGOLINE TREATMENT REVERSES LEVODOPA-INDUCED DYSKENESIAS IN PARKINSONIAN MONKEY", CLINICAL NEUROPHARMACOLOGY (2000), VOL. 23, No. 4, pp. 195-202.	
/SM/	A128	HAUSER ET AL., "PRAMIPEXOLE-INDUCED SOMNOLENCE AND EPISODES OF DAYTIME SLEEP", MOVEMENT DISORDERS (2000), Vol. 15, No. 4, pp. 658-663.	
/SM/	A129	HOMANN ET AL, "SLEEP ATTACKS IN PATIENTS TAKING DOPAMINE AGONISTS: REVIEW", BMJ JUNE 2002, Vol. 324, pp. 1483-1487.	
/SM/	A130	HUBBLE, "PRECLINICAL STUDIES OF PRAMIPEXOLE: CLINICAL RELEVANCE", EUROPEAN JOURNAL OF NEUROLOGY SUPPLEMENT (2000), 7 (SUPP. 1), PP. 15-20.	
/SM/	A131	HUBBLE, "LONG-TERM STUDIES OF DOPAMINE AGONISTS", NEUROLOGY, FEBRUARY 2002, 58 (SUPP. 1), PP. S42-S50.	
/SM	A132 /	HUTTON ET AL., "TRANSDERMAL DOPAMINERGIC D2 RECEPTOR AGONIST THERAPY IN PARKINSON'S DISEASE WITH N-0923 TDS: A DOUBLE-BLIND PLACEBO-CONTROLLED STUDY", MOVEMENT DISORDERS (2001), Vol. 16, No. 3, Pp. 459-463.	
/SM/	A133	LLEDO, "DOPAMINE AGONISTS: THE TREATMENT FOR PARKINSON'S DISEASE IN THE XX! CENTURY?", PARKINSONISM AND RELATED DISORDERS, 2001, 7, pp. 51-58.	
/SM/	A134	MARATOS ET AL., "ANTIPARKINSONIAN ACTIVITY AND DYSKINESIA RISK OF ROPINIROLE AND L-DOPA COMBINATION THERAPY IN DRUG NAÏVE MPTP-LESIONED COMMON MARMOSETS (CALLITHRIX JACCHUS)", MOVEMENT DISORDERS, 2001, Vol. 16, No. 4, pp. 631-641.	

Examiner Signature	/Snigdha Maewall/	Date Considered	05/09/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Sub	Substitute for form 1449A/PTO			Complete if Known		
000				Application Number	10/787,417	
II.	NFORMATIO	N DI	SCLOSURE	Filing Date	27 February 2004	
S	TATEMENT	BY A	APPLICANT	First Named Inventor	Chien-Hsuan HAN	
		_ , .		Art Unit	1615	
	(use as many sl	neets as	necessary)	Examiner Name	UNASSIGNED	
Sheet	9	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/SM/	A135	KIHARA ET AL., "PROTECTIVE EFFECT OF DOPAMINE D₂ AGONISTS IN CORTICAL NEURONS VIA THE PHOSPHATIDYLINOSITOL 3 KINASE CASCADE", JOURNAL OF NEUROSCIENCE RESEARCH, 2002, 70, PP. 274-282.	
/SM/	A136	KORCYZN ET AL., "ROPINIROLE VERSUS BROMOCRIPTINE IN THE TREATMENT OF EARLY PARKINSON'S DISEASE: A 6-MONTH INTERIM REPORT OF A 3-YEAR STUDY", MOVEMENT DISORDERS, 1998, Vol. 13, No. 1, Pp. 46-51.	
/SM/	A137	LANG ET AL., "CQA 206-291 IN PARKINSON'S DISEASE: A ACUTE SINGLE ESCALATING DOSAGE STUDY", THE CANADIAN JOURNAL OF NEUROLOGICAL SCIENCES, NOVEMBER 1990, Vol. 17, No. 4, PP. 416-419.	
/SM/	A138	MARATOS ET AL., "BOTH SHORT- AND LONG-ACTING D ₁ /D ₂ DOPAMINE AGONISTS INCLUDE LESS DYSKINESIA THAN L-DOPA IN THE MPTP-LESIONED COMMON MARMOSET (CALLITHRIX JACCHUS)", EXPERIMENTAL NEUROLOGY, 2003, 179, pp. 90-102.	
/SM/	A139	MAREK ET AL., "DOPAMINE AGONISTS AND PARKINSON'S DISEASE PROGRESSION: WHAT WE CAN LEARN FROM NEUROIMAGING STUDIES", ANNALS OF NEUROLOGY, 2003, Vol. 53, Supp. 3, pp. S160-S169.	
/SM/	A140	MONTASTRUC ET AL., "A RANDOMIZED CONTROLLED STUDY OF BROMOCRIPTINE VERSUS LEVODOPA IN PREVIOUSLY UNTREATED PARKINSONIAN PATIENTS: A 3 YEAR FOLLOW-UP", JOURNAL OF NEUROLOGY, NEUROSURGERY AND 'PSYCHIATRY, 1989, 52, pp. 773-775.	
/SM/	A141	MONTASTRUC ET AL., "CURRENT STATUS OF DOPAMINE AGONISTS IN PARKINSON'S DISEASE MANAGEMENT", DRUGS, 1993, 46(3), pp. 384-393.	
/SM/	A142	MONTASTRUC ET AL., "A RANDOMIZED CONTROLLED STUDY COMPARING BROMOCRIPTINE TO WHICH LEVODOPA WAS LATER ADDED, WITH LEVODOPA ALONE IN PREVIOUSLY UNTREATED PATIENTS WITH PARKINSON'S DISEASE: A FIVE YEAR FOLLOW-UP", JOURNAL OF NEUROLOGY, NEUROSURGERY AND PSYCHIATRY, 1994, 57, PP. 1034-1038.	
/SM/	A143	MONTASTRUC ET AL., "CONTROVERSY: TREATMENT OF PARKINSON'S DISEASE SHOULD BEGIN WITH A DOPAMINE AGONIST", MOVEMENT DISORDERS, 1999, Vol. 14, No. 5, PP. 725-730.	
/SM/	A144	MUNGERSDORF ET AL., "HIGH DOSE THERAPY WITH ROPINIROLE IN PATIENTS WITH PARKINSON'S DISEASE", JOURNAL OF NEURAL TRANSMISSION, 2001, 108, pp. 1309-1317.	
/SM/	A145	OLANOW ET AL., "CONTINUOUS DOPAMINE-RECEPTOR STIMULATION IN EARLY PARKINSON'S DISEASE", TRENDS. NEUROSCI., 2000, 23 (SUPPL), PP. S117-S126.	
/SM/	A146	PARKINSON STUDY GROUP, "A RANDOMIZED CONTROLLED TRIAL COMPARING PRAMIPEXOLE WITH LEVODOPA IN EARLY PARKINSON'S DISEASE: DESIGN AND METHODS OF THE CLAM-PD STUDY", CLINICAL NEUROPHARMACOLOGY, 2000, Vol. 23, No. 1, Pp. 34-44.	

Examiner	/Snigdha Maewall/	Date	05/09/2007
Signature	/Sniguria iviaewali/	Considered	03,30/2001

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Sub	stitute for form 1449A/P	TO			Complete if Known	
000				Application Number	10/787,417	
١N	IFORMATIC	ON DIS	CLOSURE	Filing Date	27 February 2004	
S	TATEMENT	BYA	PPLICANT	First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many	sheets as n	ecessary)	Examiner Name	UNASSIGNED	
Sheet	10	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/SM/	A147	O'SUILLEABHAIN ET AL., "CONTRIBUTIONS OF DOPAMINERGIC DRUGS AND DISEASE SEVERITY TO DAYTIME SLEEPINESS IN PARKINSON DISEASE", ARC. NEUROL., 2002, 59, pp. 986-989.	
/SM/	A148	PINTER ET AL., "AN OPEN-LABEL, MULTICENTRE CLINICAL TRIAL TO DETERMINE THE LEVODOPA DOSE-SPARING CAPACITY OF PRAMIPEXOLE IN PATIENTS WITH IDIOPATHIC PARKINSON'S DISEASE", JOURNAL OF NEURAL TRANSMISSION, 2000, 107, pp. 1307-1323.	
/SM/	A149	POGARELL ET AL., "PRAMIPEXOLE IN PATIENTS WITH PARKINSON'S DISEASE AND MARKED DRUG RESISTANT TREMOR: A RANDOMIZED DOUBLE-BLIND PLACEBO-CONTROLLED MULTICENTRE STUDY", JOURNAL OF NEUROLOGY, NEUROSURGERY AND PSYCHIATRY, 2002, 72, PP. 713-720.	
/SM/	A150	PARKINSON STUDY GROUP, "PRAMIPEXOLE VERSUS LEVODOPA AS INITIAL TREATMENT FOR PARKINSON'S DISEASE: A RANDOMIZED CONTROLLED STUDY", JAMA, 2000, Vol. 284, No. 15, pp. 1931-1938.	
/SM/	A151	PARKINSON STUDY GROUP, "DOPAMINE TRANSPORTER BRAIN IMAGING TO ASSESS THE EFFECTS OF PRAMIPEXOLE VERSUS LEVODOPA IN PARKINSON'S DISEASE PROGRESSION", JAMA, 2002, Vol. 287, No. 13, pp. 1653-1661.	
/SM/	A152	RASCOL ET AL., "ROPINROLE IN THE TREATMENT OF EARLY PARKINSON'S DISEASE: A 6-MONTH INTERIM REPORT FOR A 5-YEAR LEVODOPA-CONTROLLED STUDY", MOVEMENT DISORDERS, 1996, Vol. 13, No. 1, pp. 39-45.	
/SM/	A153	RASCOL, "DOPAMINE AGNOISTS: WHAT IS THE PLACE OF THE NEWER COMPOUNDS IN THE TREATMENT OF PARKINSON'S DISEASE?", JOURNAL OF NEURAL TRANSMISSIONS, 1999, (SUPP) 55, PP. 33-45.	
/SM/	A154	REICHMANN, "LONG-TERM TREATMENT WITH DOPAMINE AGONISTS IN IDIOPATHIC PARKINSON'S DISEASE", J. NEUROL., 2000, 247 (SUPP. 4), PP. IV/17-IV/19.	
/SM/	A155	RINNE ET AL., "CABERGOLINE IN THE TREATMENT OF EARLY PARKINSON'S DISEASE: RESULTS OF THE FIRST YEAR OF TREATMENT IN A DOUBLE-BLIND COMPARISON OF CABERGOLINE AND LEVODOPA", NEUROLOGY, FEBRUARY 1997, Vol. 48 (2), PP. 363-368.	
/SM/	A156	RINNE ET AL., "EARLY TREATMENT OF PARKINSON'S DISEASE WITH CABERGOLINE DELAYS THE ONSET OF MOTOR COMPLICATIONS: RESULTS OF A DOUBLE-BLIND LEVODOPA CONTROLLED TRIAL", DRUGS 55, 1998, Supp. 1, pp. 23-30.	
/SM/	A157	SCHAPIRA ET AL., "RATIONALE FOR THE USE OF DOPAMINE AGONISTS AS NEUROPROTECTIVE AGENTS IN PARKINSON'S DISEASE", ANNALS OF NEUROLOGY, 2003, Vol. 53, Supp. 3, pp. S149-S159.	
/SM/	A158	SCHULMAN, "PARKINSON'S DISEASE: THE PROPER USE OF DOPAMINE RECEPTOR AGONISTS", CURRENT TREATMENT OPTIONS IN NEUROLOGY (1999), Vol. 1, Pp. 14-20.	
/SM/	A159	SCHULMAN, "HOW TO SUCCEED IN USING DOPAMINE AGONISTS IN PARKINSON'S DISEASE", EUROPEAN JOURNAL OF NEUROLOGY SUPPLEMENT, 2000, SUPP. 1, PP. 9-13.	

Examiner Signature	/Snigdha Maewall/	Date Considered	05/09/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached.

Sut	NFORMATION DISCLOSURE STATEMENT BY APPLICANT		Complete if Known			
		•		Application Number	10/787,417	
11	NFORMATIO	N DI	SCLOSURE	Filing Date	27 February 2004	
S	STATEMENT	BY A	APPLICANT	First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many s	sheets as	necessary)	Examiner Name	UNASSIGNED	
Sheet	11	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Exeminer Initials	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/SM/	A160	STIASNY ET AL., "SAFETY OF PRAMIPREXOLE IN PATIENTS WITH RESTLESS LEGS SYNDROME", NEUROLOGY, NOVEMBER 2000, 55, pp. 1589-1590.	
/SM/	A161	TANNER, "DOPAMINE AGONISTS IN EARLY THERAPY FOR PARKINSO: I'S DISEASE", JAMA, OCTOBER 2000, Vol. 284, No. 15, pp. 1971-1973.	
/SM/	A162	TUITE ET AL., "DOPAMINE AGONISTS", SEMINARS IN NEUROLOGY, 2001, Vol. 21, NO. 1, PP. 9-14.	
/SM/	A163	METMAN ET AL., "CONTINUOUS TRANSDERMAL DOPAMINERGIC STIMULATION IN ADVANCED PARKINSON'S DISEASE", CLINICAL NEUROPHARMACOLOGY, 2001, Vol. 24, No. 3, pp. 163-169.	
/SM/	A164	WEINER ET AL., "THE LONG-TERM SAFETY AND EFFICACY OF PRAMIPEXOLE IN ADVANCED PARKINSON'S DISEASE", PARKINSONISM AND RELATED DISORDERS, 2001, 7, PP. 115-120.	
/SM/-	A165	WHONE ET AL., "SLOWER PROGRESSION OF PARKINSON'S DISEASE WITH ROPINIROLE VERSUS LEVODOPA: THE REAL-PET STUDY", ANNALS OF NEUROLOGY, 2003, 54, PP. 93-101.	
/SM/	A166	WILLIAMS ET AL., "IMPROVED THERAPIES FOR PARKINSON'S DISEASE: LIFE BEYOND DOPAMINE D2/D3 RECEPTOR AGONISTS", TIPS, SEPTEMBER 1997, Vol. 18, pp. 307-310.	
/SM/	A167	AHTILA ET AL., "EFFECTS OF ENTACAPONE, A COMT INHIBITOR, ON THE PHARMOCOKINETICS AND METABOLISM OF LEVODOPA AFTER ADMINISTRATION OF CONTROLLED-RELEASE LEVODOPA-CARBIDOPA IN VOLUNTEERS", CLINICAL NEUROPHARMACOLOGY, 1995, Vol. 18, No. 1, pp. 46-57.	
/SM/	A168	BAAS ET AL., "PHARMACOKINETIC-PHARMACODYNAMIC RELATIONSHIP OF LEVODOPA WITH AND WITHOUT TOLCAPONE IN PATIENTS WITH PARKINSON'S DISEASE", CLINICAL PHARMACOKINET, 2001, 40(5), PP. 383-393.	
/SM/	A169	BROOKS ET AL., "ENTACAPONE IS BENEFICIAL IN BOTH FLUCTUATING AND NON-FLUCTUATING PATIENTS WITH PARKINSON'S DISEASE: A RANDOMIZED, PLACEBO CONTROLLED, DOUBLE BLIND, 6-MONTH STUDY", JOURNAL OF NEUROLOGY, NEUROSURGERY AND PSYCHIATRY, 2003, 74, PP. 1071-079.	
/SM/	A170	CHONG ET AL., "ENTACAPONE", THE ANNALS OF PHARMACOTHERAPY, SEPTEMBER 2000, VOL. 34, PP. 1056-1065.	
/SM/	A171	DA PRADA ET AL., "IMPROVED THERAPIES OF PARKINSON'S DISEASE WITH TOLCAPONE, A CENTRAL OF PERIPHERAL COMT INHIBITOR WITH AN S-ADENOSYL-L-METHIONINE-SPARING EFFECT", CLINICAL NEUROPHARAMOLOY, 1994, Vol. 17, Supp. 3, pp. S26-S37.	
/SM/	A172	DAVIS ET AL., "ACUTE EFFECTS OF COMT INHIBITION ON L-DOPA PHARMACOKINETICS IN PATENTS TREATED WITH CARBIDOPA AND SELEGILINE", 1995, Vol. 18, No. 4, Pp, 333-337.	
/SM/	A173	DE SANTI ET AL., "CATCHOL-O-METHYLTRANSFERESE: VARIATIONS IN ENZYME ACTIVITY AND INHIBITION BY ENTRTOLCAPONE AND TOLCAPONE,", EUROPEAN JOURNAL OF CLINICAL PHARMACOLOGY, 1998, 54, pp. 215-219.	
/SM/	A174	GASSER ET AL., "COMT INHIBITION BY TOLCAPONE FURTHER IMPROVES LEVODOPA PHARMACOKINETICS WHEN COMBINED WITH A DUAL-RELEASE FORMULATION OF LEVODOPA/BENSERAZIDE", EUROPEAN NEUROLOGY, 1999, 41, pp. 206-211.	

Examiner	/Colodles Messell/	Date	05/00/2007
Signature	/Snigdha Maewall/	Considered	05/09/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

Sub	Substitute for form 1449A/PTO			Complete if Known		
				Application Number	10/787,417	
IN	NFORMATIC	N DI	SCLOSURE	Filing Date	27 February 2004	
S	TATEMENT	BY	APPLICANT	First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many sheets as necessary)			Examiner Name	UNASSIGNED	
Sheet	12	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/SM/		DELEU et al., "The Effect of Carbidopa and Entacapone Pretreatment on the L-Dopa Pharmacokinetics and Metabolism in Blood Plasma and Skeletal Muscle in Beagle Dog: An <i>IN VIVO</i> Microdialysis Study", The Journal of Pharmacology and Experimental Therapeutics, 1995, Vol. 273, No. 3, pp. 1323-1331.	
/SM/	A176	DINGEMANSE, "Issues Important for Rational COMT Inhibition", Neurology, 2000, 55, (Supp. 4), pp. S24-S27.	
/SM/	A177	FORSBERG ET AL., "PHARMACODYNAMIC RESPONSE OF ENTACAPONE IN RATS AFTER AMDINISTRATION OF ENTACAPONE FORMULATIONS AND PRODRUGS WITH VARYING BIOAVAILABILITIES", PHARMACOLOGY & TOXICOLOGY, 2002, 304, pp. 49-503.	
/SM/	A178	GOETZ, "INFLUENCE OF A COMT INHIBITION ON LEVODOPA PHARMACOLOGY AND THERAPY", NEUROLOGY, 1998, 50 (SUPP. 5), S26-S30.	
/SM/	A179	GUTTMAN ET AL., "ADMINISTRATION OF THE NEW COMT INHIBITOR OR-611 INCREASES STRIATAL UPTAKE OF FLUORODOPA", MOVEMENT DISORDERS, 1993, Vol. 8, No. 3, pp. 298-304.	
/SM/	A180	HAASIO ET AL., "COMPARATIVE TOXICOLOGICAL STUDY ON THE HEPATIC SAFETY OF ENTACAPONE AND TOLCAPONE IN THE RAT", JOURNAL OF NEURAL TRANSMISSION, 2001, 108, pp. 79-91.	
/SM/	A181	HAUSER, "LEVODOPA/CARBIDOPA/ENTACAPONE (STALEVO)", NEUROLOGY, 2004, 62 (SUPP. 1), PP. S64-S71.	
/SM/	A182	HEIKKINEN ET AL., "PHARMACOKINETICS OF ENTACAPONE, A PERIPHERALLY ACTING CATECHOL-O-METHYLTRANSFERASE INHIBITOR, IN MAN", EUROPEAN JOURNAL OF CLINICAL PHARMACOLOGY, 2001, 56, Pp. 821-826.	
/SM	A183	HEIKKINEN ET AL., "THE EFFECTS OF DIFFERENT REPEATED DOSES OF ENTACAPONE ON THE PHARMACOKINETICS OF L-DOPA AND ON THE CLINICAL RESPONSE TO L-DOPA IN PARKINSON'S DISEASE", CLINICAL NEUROPHARMACOLOGY, 2001, Vol. 24, No. 3, pp. 150-157.	
/SM/	A184	HEIKKINEN ET AL., "ENTACAPONE IMPROVES THE AVAILABILITY OF L-DOPA IN PLASMA BY DECREASING ITS PERIPHERAL METABOLISM INDEPENDENT OF L-DOPA/CARBIDOPA DOSE", BR. J. CLIN. PHARMACOL., 2002, 54, pp. 363-371.	
/SM/	A185	HOLM ET AL., "ENTACAPONE", DRUGS, JULY 1999, 58(1), PP. 159-177.	
/SM/	A186	JORGA ET AL., "PHARMACOKINETICS AND PHARMACODYNAMICS AFTER ORAL AND INTRAVENEOUS ADMINISTRATION OF TOLCAPONE, A NOVEL ADJUNCT TO PARKINSON'S DISEASE THERAPY", EUROPEAN JOURNAL OF PHARMACOLOGY, 1998, 54, pp. 443-447.	
/SM/	A187	KAAKKOLA ET AL., "GENERAL PROPERTIES AND CLINICAL POSSIBILITIES OF NEW SELECTIVE INHIBITORS OF CATECHOL-O-METHYLTRANSFERASE", GEN. PHARMAC., 1994, VOL, 25, No. 5, PP. 813-824.	
/SM/	A188	KAAKKOLA ET AL., "EFFECT OF ENTACAPONE, A COMT INHIBITOR, ON CLINICAL DISABILITY AND LEVODOPA METABOLISM IN PARKINSONIAN PATIENTS", NEUROLOGY, 1994, 44, PP. 77-80.	
/SM/	A189	KAAKKOLA, "CLINICAL PHARMACOLOGY, THERAPEUTIC USE AND POTENTIAL OF COMT INHIBITORS IN PARKINSON'S DISEASE", DRUGS, 2000, 59(6), PP. 1233-1250.	

Examiner	/Snigdha Maewall/	Date	05/09/2007
Signature	70111garia Maomalii	Considered	03/03/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Oraw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449A/PTO Application Number 10/787,417 INFORMATION DISCLOSURE 27 February 2004 Filing Date STATEMENT BY APPLICANT Chien-Hsuan HAN First Named Inventor Art Unit 1615 (use as many sheets as necessary) **UNASSIGNED Examiner Name** 49393-00004 13 18 Attorney Docket Number Sheet

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/SM	A190	KERÄNEN ET AL., "THE EFFECT OF CATECHOL-O-METHYLTRANSFERASE INHIBITION BY ENTACAPONE ON THE PHARMACOKINETICS AND METABOLISM OF LEVODOPA IN HEALTHY VOLUNTEERS", CLINICAL NEUROPHARMACOLOGY, 1993, Vol. 16, No. 2, Pp. 145-156.	
/SM	A191	KERÄNEN ET AL., "INHIBITION OF SOLUABLE CATECHOL-OMETHYLTRANSFERASAE AND SINGLE DOSE PHARMACOKINETICS AFTER ORAL AND INTRAVENOUS ADMINISTRATION OF ENTACAPONE", J. CLIN. PHARMACOL., 1994, 46, pp. 151-157.	
/SM/	A192	KOLLER ET AL., "RANDOMIZED TRIAL OF TOLCAPONE VERSUS PERSOLIDE AS ADD-ON TO LEVODOPA THERAPY IN PARKINSON'S DISEASE PATIENTS WITH MOTOR FLUCTUATIONS", MOVEMENT DISORDERS, 2001, Vol. 16, No. 5, pp. 858-866.	
/SM	A193 /	LÉGER ET AL., "EFFECT OF CATECHOL-O-METHYLTRANSFERASE INHIBITION ON RAIN UPTAKE OF [18F]FLURODOPA: IMPLICATIONS FOR COMPARTMENTAL MODELING AND CLINICAL USEFULNESS" SYNAPSE, 1998, 30, pp. 351-361.	
19111	A194	LEPPÄNEN ET AL., "SYNTHESIS AND IN-VITRO/IN-V-VO EVALUATION OF ORALLY ADMINISTERED ENTACPONE PRODRUGS", JOURNAL OF PHARMACOLOGY, 2001, 53, PP. 1489-1498.	
/SM/	A195	WITH PARKINSON'S DISEASE", 1997, VOL. 12, NO. 4, PP. 497-505.	
/SM/	A196	MARTINEZ-MARTIN ET AL., "EXTENDING LEVODOPA ACTION: COMT INHIBITION", NEUROLOGY, JUNE 1998, 50 (Supp. 6), pp. S27-S32.	
/SM/	A197	MERELLO ET AL., "EFFECT OF ENTACAPONE, A PERIPHERALLY ACTING CATECHOL-O-METHYLTRANSFERASE INHIBITOR ON THE MOTOR RESPONSE TO ACUTE TREATMENT WITH LEVODOPA IN PATIENTS WITH PARKINSON'S DISEASE", JOURNAL OF NEUROLOGY, NEUROSURGERY AND PSYCHIATRY, 1994, 57, pp. 186-189.	
/SM/	A198	MYLLYLÄ ET AL., "EFFECT OF ENTACAPONE, A COMT INHIBITOR, ON THE PHARMACOKINETICS OF LEVODOPA AND ON CARDIOVASCULAR RESPONSES IN PATIENTS WITH PARKINSON'S DISEASE", EURO. J. CLIN. PHARMACOL., 1993, 45, PP. 419-423.	
/SM/	A199	NAJIB, "ENTACAPONE: A CATHECHOL-O-METHYLTRANSFERASE INHIBITOR FOR THE ADJUNCTIVE TREATMENT OF PARKINSON'S DISEASE", CLINICAL THERAPEUTICS, 2001, Vol. 23, No. 6., pp. 802-832.	
/SM/	A200	NAPOLITANO, ET AL., "EFFECTS OF TOLCAPONE, A NOVEL CATECHOL-O-METHYLTRANSFERASE INHIBITOR, ON STRIATAL METABOLISM OF L-DOPA AND DOPAMINE IN RATS", EUROPEAN JOURNAL OF PHARMACOLOGY, 1995, 273, pp. 215-221.	
/SM/	A201	NUTT, "CATECHOL-O-METHYLTRANSFERASE INHIBITION ON THE PHARMACOKINETICS AND PHARMACODYNAMICS OF LEVODOPA IN PARKINSONIAN PATIENTS" NEUROLOGY, MAY 1994, 44, PP. 913-919.	
	A202	NUTT, "CATECHOL-O-METHYLTRANSFERASE INHIBITORS FOR TREATMENT OF PARKINSON'S DISEASE", THE LANCET, 1998, Vol. 351, pp. 1221-1222.	
/SM/	A203	NUTT, CATECHOL-O-METHYLTRANSFERASE INHIBITION AND THE TREATMENT OF PARKINSON'S DISEASE®, Advances in Pharmacology, 1998, Vol. 42, pp. 332-334.	

Examiner	/Spiedbo Magwall/	Date	05/00/0007
Signature	/Snigdha Maewall/	Considered	05/09/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached.

Sub	stitute for form 1449A/P	TO		Complete if Known			
Substitute for form 1440AF 10				Application Number	10/787,417		
11	NFORMATIC	N DIS	CLOSURE	Filing Date .	27 February 2004		
S	STATEMENT BY APPLICANT			First Named Inventor	Chien-Hsuan HAN		
				Art Unit	1615		
	(use as many	sheets as ne	cessary)	Examiner Name	UNASSIGNED		
Sheet	14	of	18	Attorney Docket Number	49393-00004		

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/SM/	A204	NUTT, "EFFECT OF COMT INHIBITION ON THE PHARMACOKINETICS AND PHARMACODYNAMICS OF LEVODOPA IN PARKINSONIAN PATIENTS", NEUROLOGY, 2000, 55 (SUPP 4), PP. S33-S41.	
/SM/	A205	PALMER et al., "Cost Effectiveness of Treatment of Parkinson's Disease with Entacapone in the United States", Pharmacoeconomics, 2002, 20(9), pp. 617-628.	
/SM/	A206	PICCINI ET AL., "THE CATECHOL-O-METHYLTRANSFERASE (COMT) INHIBITOR ENTACAPONE ENHANCES THE PHARMACOKINETIC AND CLINICAL RESPONSE TO SINEMET CR IN PARKINSON'S PATIENTS", JOURNAL OF NEUROLOGY, NEUROSURGERY AND PSYCHIATRY, 2000, 68, pp. 589-594.	
/SM/	A207	ROURU ET AL., "PHARMACOKINETICS OF ORAL ENTACAPONE AFTER FREQUENT MULTIPLE DOSING AND EFFECTS ON LEVODOPA DISPOSITION", EUR. J. CLIN. PHARMACOL., 1999, 55, PP. 461-467.	
/SM/	A208	RUOTTINEN ET AL., "EFFECT OF ONE MONTH'S TREATMENT WITH PERIPHERALLY ACTING CATECHOL-O-METHYLTRANSFERASE INHIBITOR, ENTACAPONE ON PHARMACOKINETICS AND MOTOR RESPONSE TO LEVODOPA IN ADVANCED PARKINSONIAN PATIENTS", CLINICAL NEUROPHARMACOLOGY, 1996, Vol. 19, No. 3, PP. 222-223.	
/SM/	A209	RUOTTINEN ET AL., "A DOUBLE-BLIND PHARMACOKINETIC AND CLINICAL DOSE-RESPONSE STUDY OF ENTACAPONE AS AN ADJUVANT TO LEVODOPA TREATMENT IN ADVANCED PARKINSON'S DISEASE", CLINICAL NEUROPHARMACOLOGY, 1996, Vol. 19, No. 4, pp. 283-296.	
/SM/	A210	RUOTTINEN ET AL., "ENTACAPONE PROLONGS LEVODOPA RESPONSE IN A ONE MONTH DOUBLE BLIND STUDY IN PARKINSONIAN PATIENTS WITH LEVODOPA RELATED FLUCTUATIONS", JOURNAL OF NEUROLOGY, NEUROSURGERY AND PSYCHIATRY, 1996, 60, pp. 36-40.	
/SM/	A211	RUOTTINEN ET AL., "COMT INHIBITION IN THE TREATMENT OF PARKINSON'S DISEASE", JOURNAL OF NEUROLOGY, 1998, 245 (SUPP. 3), PP. P25-P34.	
/SM/	A212	SAWLE ET AL., "THE EFFECT OF ENTACAPONE (OR-611) ON BRAIN [18F]-6-L-FLURODOPA METABOLISM: IMPLICATIONS FOR LEVODOPA THERAPY OF PARKINSON'S DISEASE", NEUROLOGY, JULY 1994, 44, pp. 1292-1297.	
/SM/	A213	TRÓCONIZ ET AL., "POPULATION PHARMACODYNAMIC MODELING OF LEVODOPA IN PATIENTS WITH PARKINSON'S DISEASE RECEIVING ENTACAPONE", CLINICAL PHARMACOLOGY AND THERAPEUTICS, 1998, Vol. 64, No. 1, pp. 106-116.	
/SM/	A214	ZHU, "CATECHOL-O-METHYLTRANSFERASE (COMT) — MEDIATED METHYLATION METABOLISM OF EDOGENOUS BIOACTIVE CATECHOLS AND MODULATION BY ENDOBIOTICS AND XENOBIOTICS: IMPORTANCE OF PATHOPHYSIOLOGY AND PATHOGENESIS", CURRENT DRUG METABOLISM, 2002, Vol. 3, pp. 321-349.	
/SM/	A215	ALEXANDER et al., "B2-Adrenergic Agonist as Adjunct Therapy to Levodopa in Parkinson's Disease", Neurology, 1994, 44, pp. 1511-1513.	

Examiner	/Snigdha Maewall/	Date	05/00/2007
Signature	/Orligaria Macwall/	Considered	05/09/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO				Complete if Known		
				Application Number	10/787,417	
II.	NFORMATIC	N DIS	CLOSURE	Filing Date	27 February 2004	
S	STATEMENT BY APPLICANT			First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many	sheets as ne	ncessary)	Examiner Name	UNASSIGNED	
Sheet	15	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T2
/SM/	A216	BAYES ET AL., "GATEWAYS TO CLINICAL TRIALS", METHODS FIND EXP. CLIN. PHARMACOL., APRIL 2003, 25(3), PP. 225-248.	
/SM/	A217	BONUCCELLI ET AL., "DEXTROMETHORPHAN AND PARKINSONISM", THE LANCET, JULY 1992, VOL. 340, PP. 53.	
/SM/	A218	GOETZ ET AL., "OBJECTIVE CHANGES IN MOTOR FUNCTION DURING PLACEBO TREATMENT IN PD", NEUROLOGY, 2000, 54, PP. 710-714.	
/SM/	A219	JIMENEZ, ET AL., "NARROW BENEFICIAL EFFECT OF DEXTROMETHORPHAN ON LEVODOPA-INDUCED MOTOR RESPONSE ALTERATIONS IN AN EXPERIMENTAL MODEL OF PARKINSONISM", BRAIN RESEARCH, 1999, 839, Pp. 190-193.	
/SM/	A220	JOLIVALT ET AL., "DEXTROMETHORPHAN O-DEMETHYLASE ACTIVITY IN RAT BRAIN MICROSOMES", NEUROSCIENCE LETTERS, 1995, 187, pp. 65-68.	
/SM/	A221	MARIN ET AL., MK-801 PREVENTS LEVODOPA-INDUCED MOTOR RESPONSE ALTERATIONS IN PARKINSONIAN RATS", BRAIN RESEARCH, 1996, 736, pp. 202-205.	
/SM	A222	MERELLO ET AL., "EFFECT OF MEMANTINE (NMDA ANTAGONIST) ON PARKINSON'S DISEASE: A DOUBLE-BLIND CROSSOVER RANDOMIZED STUDY", CLINICAL NEUROPHARMACOLOGY, 1999, Vol. 22, No. 5, pp. 273-276.	
/SM/	A223	MONTASTRUC ET AL., "N-METHYL-D-ASPARTATE (NMDA) ANTAGONIST AND PARKINSON'S DISEASE: A PILOT STUDY WITH DEXTROMETHORPHAN", MOVEMENT DISORDERS, 1994, Vol. 9, No. 2, pp. 242-243.	
/SM/	A224	MONTASTRUC ET AL., "GLUTAMATE ANTAGONISTS AND PARKINSON'S DISEASE: A REVIEW OF CLINICAL DATA", NEUROSCIENCE AND BIOBEHAVIORAL REVIEWS, 1997, Vol. 21, No. 4, pp. 477-480.	
/SM/	A225	MONTASTRUC ET AL., "MODAFINIL AND PRAMIPEXOLE-ASSOCIATED SOMNOLENCE", MOVEMENT DISORDERS, 2001, Vol. 16, No. 4, pp. 783-784.	
/SM/	A226	PEARCE ET AL., "THE MONOAMINE REUPTAKE BLOCKER BRASOFENSINE REVERSES AKINESIA WITHOUT DYSKINESIA IN MPTP-TREATED AND LEVODOPA-PRIMED COMMON MARMOSETS", MOVEMENT DISORDERS, 2002, Vol. 17, No. 5, pp. 877-886.	
/SM/	A227	PRZUNTEK ET AL., "BUDAPINE PROVIDES ADDITIONAL BENEFIT IN PATIENTS WITH PARKINSON DISEASE RECEIVING A STABLE OPTIMUM DOPAMINERGIC DRUG REGIMEN", ARCH. NEUROL., 2002, 59, PP. 803-806.	
/SM	A228 /	PARKINSON STUDY GROUP, "EFFECTS OF TOCOPHEROL AND DEPRENYL ON THE PROGRESSION OF DISABILITY IN EARLY PARKINSON'S DISEASE", NEW ENGLAND JOURNAL OF MEDICINE, JANUARY 1993, Vol. 328(3), pp. 176-183.	

Examiner Signature	/Snigdha Maewall/	Date Considered	05/09/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Sut	ostitute for form 1449A/PTO			Complete if Known		
			•	Application Number	10/787,417	
11	NFORMATION	1 DI	SCLOSURE	Filing Date	27 February 2004	
S	STATEMENT BY APPLICANT			First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many she	eets as	necessary)	Examiner Name	UNASSIGNED	
Sheet	16	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/SM/	A229	QIN, ET AL., "STIMULATION OF N-METHYL-D-ASPARATE RECEPTORS INDUCES APOPTOSIS IN RAT BRAIN", BRAIN RESEARCH, 1996, 725, PP. 166-176.	
/SM/	A230	RAMPELLO ET AL., "THE SSRI, CITALOPRAM, IMPROVES BRADYKINESIA IN PATIENTS WITH PARKINSON'S DISEASE TREATED WITH L-DOPA", CLINICAL NEUROPHARMACOLOGY, 2002, VOL. 25, NO. 1, PP. 21-24.	
/SM/	A231	RASCOL ET AL.," TWO WEEKS OF TREATMENT WITH DEPRENYL (SELEGILINE) DOES NOT PROLONG L-DOPA EFFECT IN PARKINSONIAN PATIENTS: A DOUBLE-BLIND CROSSOVER PLACEBO-CONTROLLED TRIAL", NEUROLOGY, 1988, 38, pp. 1387-1391.	
/SM/	A232	SHOULSON ET AL., "IMPACT OF SUSTAINED DEPRENYL (SELEGILINE) IN LEVODOPA-TREATED PARKINSON'S DISEASE: A RANDOMIZED PLACEBO-CONTROLLED EXTENSION OF THE DEPRENYL AND TOCOPHEROL ANTIOXIDATIVE THERAPY OF PARKINSONISM TRIAL", ANN. NEUROL., MAY 2002, 51, PP. 604-612.	
/SM/	A233	STERNIC, ET AL., "THE THERAPEUTIC EFFECT OF MOCLOBEMIDE, A REVERSIBLE SELECTIVE MONOAMINE OXIDASE A INHIBITOR, IN PARKINSON'S DISEASE", CLINICAL NEUROPHARMACOLOGY, 1998, Vol. 21, No. 2, pp. 93-96.	
/SM/	A234	TANAKA ET AL., "POSSIBILITY OF NON-IMMUNOSUPPRESSIVE IMMUNOPHILIN LIGANDS AS POTENTIAL THERAPEUTIC AGENTS FOR PARKINSON'S DISEASE", CURRENT PHARMACEUTICAL DESIGN, 2004, 10, pp. 669-677.	
/SM/	A235	THOMAS ET AL., "MINOCYCLINE AND OTHER TETRACYCLINE DERIVATIVES: NEUROPROTECTIVE STRATEGY IN PARKINSON'S DISEASE AND HUNTINGTON'S DISEASE", CLINICAL NEUROPHARMACOLOGY, 2003, 26(1), pp. 18-23.	
/SM/	A236	THOMAS ET AL., "MINOCYCLINE: NEUROPROTECTIVE MECHANISMS IN PARKINSON'S DISEASE", CURRENT PHARMACEUTICAL DESIGN, 2004, 10, pp. 679-686.	
/SM/	A237	METMAN ET AL., "A TRIAL OF DEXOMETHORPHAN IN PARKINSONIAN PATIENTS WITH MOTOR RESPONSE COMPLICATIONS", MOVEMENT DISORDERS, 1998, Vol. 13, No. 3, pp. 414-417.	
/SM/	A238	METMAN ET AL., "DEXTROMETHORPHAN IMPROVES LEVODOPA-INDUCED DYSKINESIAS IN PARKINSON'S DISEASE", NEUROLOGY, 1998, 51, pp. 203-206.	
/SM/	A239	BETTINI ET AL., "Influence of Layer Position on In Vitro and In Vivo Release of Levodopa Methyl Ester and Carbidopa From Three-Layer Matrix Tablets", European Journal of Pharmaceutics and Biopharmaceutics, 2002, 53, pp. 227-232.	
/SM/	A240	DELEU ET AL., "CLINICAL AND PHARMACOKINETIC COMPARISON OF ORAL AND DUODENAL DELIVERY OF LEVODOPA/CARBIDOPA IN PATIENTS WITH PARKINSON'S DISEASE WITH A FLUCTUATING RESPONSE TO LEVODOPA", EUROPEAN JOURNAL OF CLINICAL PHARMACOLOGY, 1991, 41, PP. 453-458.	
/SM/	A241	DURSO ET AL., "VARIABLE ASORPTION OF CARBIDOPA AFFECTS BOTH PERIPHERAL AND CENTRAL LEVODOPA METABOLISM", JOURNAL OF CLINICAL PHARMACOLOGY, 2000, 40, Pp. 854-860.	
/SM/	A242	GRANGE ET AL., "A PHARMACOKINETIC MODEL TO PREDICT THE PK INTERACTION OF L-DOPA AND BENSERAZIDE IN RATS", PHARMACEUTICAL RESEARCH, 2001, Vol. 18, No. 8, Pp. 1174-1184.	
/SM/	A243	MIZUTANI ET AL., "PHARMACOKINETIC MODEL OF ORAL LEVODOPA AND ROLE OF CARBIDOPA IN PARKINSON'S PATIENTS", BIOL. PHARM. BULL., DECEMBER 1995, Vol. 18(12), pp. 1729-1737.	

Examiner	/Snigdha Maewall/	Date	05/09/2007
Signature	/Orligaria iviaewali/	Considered	03/03/2007

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Sut	ostitute for form 1449A/P	סזי			Complete if Known	
				Application Number	10/787,417	
11	NFORMATIC	ON DIS	CLOSURE	Filing Date	27 February 2004	
5	STATEMENT	BY AF	PPLICANT	First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
l	(use as many	sheets as ne	cessary)	Examiner Name	UNASSIGNED	
Sheet	17	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.'	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²		
/SM/	CLINICAL NEUROPHARMACOLOGY, 1994, VOL. 17, NO. 5, PP. 429-434.				
/SM/ HUTTON ET AL., "PROLONGED SERUM LEVODOPA LEVELS WITH CONTROLLED-RELEASE CARBIDOPA LEVODOPA IN THE TREATMENT OF PARKINSON'S DISEASE", ARCH. NEUROL., JANUARY 1988, Vol. 45 pp. 55-57.					
/SM/ A246 KAAKKOLA ET AL., "THE EFFECT OF AN INCREASED RATIO OF CARBIDOPA TO LEVODOPA ON THE PHARMACOKINETICS OF LEVODOPA", ACTA. NEUROL. SCAND., 1985, VOL. 72, PP. 385-391.					
/SM/	A247	KARUMA ET AL., "COMPARATIVE INVESTIGATION OF INHIBITORS OF EXTRACEREBRAL DOPA DECARBOXYLASE IN MAN AND RATS", J. PHARMA. PHARMAC., 1972, Vol. 24, Pp. 289-294.			
/SM/	A248	NELSON ET AL., "PHARMACODYNAMIC MODELING OF CONCENTRATION-EFFECT RELATIONSHIPS AFTER CONTROLLED-RELEASE CARBIDOPA/LEVODOPA (SINEMET CR4) IN PARKINSON'S PATIENTS", NEUROLOGY, JANUARY 1990, 40, pp. 70-74.			
/SM/	A249	PAHWA ET AL., "EARLY MORNING AKINESIA IN PARKINSON'S DISEASE: EFFECT OF STANDARD CARBIDOPA/LEVODOPA AND SUSTAINED-RELEASE CARBIDOPA/LEVODOPA", NEUROLOGY, APRIL 1996, 46, PP. 1059-1062.			
A250 PAHWA ET AL., "COMPARISON OF STANDARD CARBIDOPA-LEVODOPA AND SUSTAINED-RELEASE CARBIDOPA-LEVODOPA IN PARKINSON'S DISEASE: PHARMACOKINETIC AND QUALITY OF LIFE MEASURES", MOVEMENT DISORDERS, 1997, Vol. 12, No. 5, pp. 677-681.					
/SM/	A251	ROBERTSON ET AL., "THE EFFECT OF AGE ON THE PHARMACOKINETICS OF LEVODOPA ADMINISTERED ALONE AND IN THE PRESENCE OF CARBIDOPA", BR. J. CLIN. PHARMAC., 1989, 28, PP. 61-69.			
/SM/	A252	SAGAR ET AL., "BIOAVAILABILITY STUDIES OF ORAL DOSAGE FORMS CONTAINING LEVODOPA AND CARBIDOPA USING COLUMN-SWITCHING CHROMATOGRAPHY FOLLOWED BY ELECTROCHEMICAL DETECTION", THE ROYAL SOCIETY OF CHEMISTRY, 2000, 125, pp. 439-445.			
/SM/	A253	SAGE ET AL., "PHARMACOKINETICS OF CONTINUOUS-RELEASE CARBIDOPA/LEVODOPA", CLINICAL NEUROPHARMACOLOGY, 1994, Vol. 17, Supp. 2, pp. S1-S6.			
/SM/	A254	METMAN ET AL., "FLUCTUATIONS IN PLASMA LEVODOPA AND MOTOF, RESPONSES WITH LIQUID AND TABLET LEVODOPA/CARBIDOPA", MOVEMENT DISORDERS, 1994, Vol. 9, No. 4, Pp. 463-465.			
/SM/	A255	YEH et al., "Pharmacokinetics and Bioavailability of Sinemet CR: A Summary of Human Studies", Neurology, November 1989, 39 (Supp. 2), pp. 25-38.			
/SM	A256	BARTHOLINI ET AL., "EFFECT OF VARIOUS DECARBOXYLASE INHIBITORS ON THE CEREBRAL METABOLISM OF DIHYDROXYPHENALALANINE", J. PHARM. PHARMAC., 1969, 21, PP. 323-324.			

Examiner		Date	05/09/2007
Cxammer	10 - 1 - 10 - 14 11/	Date	1 115/114/2007
01	/Snigdha Maewall/	0	00/00/2007
Signature	/Snigdha Maewall/	l Considered	

^{*}EXAMINER: Initial If reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). ³Applicant is to place a check mark here if English language Translation is attached.

Su	bstitute for form 1449A/P	то		Complete if Known		
1				Application Number	10/787,417	
11	NFORMATIC	ON DIS	SCLOSURE	Filing Date	27 February 2004	
STATEMENT BY APPLICANT				First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many	sheets as i	necessary)	Examiner Name	UNASSIGNED	
Sheet	18	of	18	Attorney Docket Number	49393-00004	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²		
-7SM/	A257	DELEU ET AL., "THE EFFECT OF CARBIDOPA ON THE PHARMACOKINETICS AND METABOLISM OF			
		INTRAVENOUSLY ADMINISTERED LEVODOPA IN BLOOD PLASMA AND SKELETAL MUSCLES", ARCH. PHARMACOL., 1993, 348, pp. 576-581.			
/SM/	A258	DIEDERICH ET AL., "EFFECTS OF L-DOPA/CARBIDOPA ADMINISTRATION ON THE LEVELS OF L-DOPA, OTHER AMINO ACIDS AND RELATED COMPOUNDS IN THE PLASMA, BRAIN AND HEART OF THE RAT", PHARMACOLOGY, 1997, 55, PP. 109-116.			
/SM/	OTOTELINO E-DOTA ELEVEED IN TOTA , I TIANIMADED TIGAE (LEDEAROIT, 1000, 102: 0, 110: 0:				
/SM/ A260 OBACH ET AL., "THE PHARMACOKINETIC PROFILE OF CARBIDOPA IN DOGS", J. PHARM. PHARMACOL., 1984, 36, PP. 415-416.					
/SM/	A261	RAUWS ET AL., "COMPARATIVE 90-DAY TOXICITY OF TWO DECARBOXYLASE INHIBITORS, BENSERAZIDE, AND CARBIDOPA IN THE RAT", TOXICOLOGY AND APPLIED PHARMACOLOGY, 1982, 66, PP. 201-220.			
/SM/	A262	ROSE ET AL., "THE EFFECT OF CARBIDOPA ON PLASMA AND MUSCLE LEVELS OF L-DOPA, DOPAMINE AND THEIR METABOLITES FOLLOWING L-DOPA ADMINISTRATION TO RATS", MOVEMENT DISORDERS, 1988, Vol. 3, No. 2, Pp. 117-125.			
/SM/	A263	ROSE, ET AL., "PERIPHERAL PHARMACOKINETIC HANDLING AND METABOLISM OF L-DOPA IN THE RAT: THE EFFECT OF ROUTE OF ADMINISTRATION AND CARBIDOPA PRETREATMENT", J. PHARM. PHARMACOL., 1991, 43, Pp. 325-330.			
/SM/	A264	SHELTON ET AL., "METABOLISM OF CARBIDOPA TO ALPHAMETHYLDOPAMINE AND ALPHAMETHYLNOREPINEPHERINE IN RATS", BIOCHEMICAL PHARMACOLOGY, 1985, Vol. 34, No. 20, PP. 3623-3626.			
/SM/	A265	VICKERS ET AL., "METABOLISM OF CARBIDOPA [L~(-)~A-HYDRAZINO-3,4 DIHYDROXY- A-METHYLDYDROCINNAMIC-ACID MONOHYDRATE], AN AROMATIC AMINO ACID DECARBOXYLASE INHIBITOR, IN THE RAT, DOG, RHESUS MONKEY AND MAN", DRUG METABOLISM AND DEPOSITION, 1974, Vol. 2, No. 1, Pp. 9-23.			
/SM/	A266	VICKERS ET AL., "FURTHER STUDIES ON THE METABOLISM OF CARBIDOPA, (-)-L &-HYDRAZINO-3,4 DIHYDROXY- A-METHYLBENZENEPROPANOIC ACID MONOHYDRATE IN THE HUMAN, RHESUS MONKEY, DOG AND RAT", JOURNAL OF MEDICINAL CHEMISTRY, 1975, Vol. 18, No. 2, pp. 134-138.			
/SM/	A267	ZWICKEY ET AL., "PRECLINICAL TOXICOLOGICAL STUDIES OF CARBIDOPA AND COMBINATIONS OF CARBIDOPA AND LEVODOPA", TOXICOLOGY AND APPLIED PHARMACOLOGY, 1974, 29, PP. 181-195.			
/SM/	A268	GRAHNEN ET AL., "COMPARATIVE MULTIPLE-DOSE PHARMACOKINETICS OF CONTROLLED-RELEASE LEVODOPA PRODUCTS", EUR. NEUROL., 1992, Vol. 32, pp. 343-348.			
/SM/	A269	DESCOMBES ET AL., "DUAL-RELEASE FORMULATION, A NOVEL PRINCIPLE IN L-DOPA TREATMENT OF PARKINSON'S DISEASE", NEUROLOGY 56, MAY (1 OF 2) 2001, Pp. 1239-1242.			
/SM/	A270	HEIKKENEN ET AL., "New Levodopa, Carbidopa and Entacapone Combination Tablets", European Journal of Neurology, 2003, 10 (Supp. 1), pp. 25-204.			
121/1		EUROPEAN JOURNAL OF NEUROLOGY, 2003, 10 (SUPP. 1), PP. 25-204.	L		

Signature Considered U3/U9/2007	Examin Signatu	1 John John January Ja	Date Considered	05/09/2007
-------------------------------------	-------------------	--	--------------------	------------

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Under the Paperwork Reduction De

Sub	stitute for form 1449A/F	то		Complete If Known		
				Application Number	10/787,417	
l in	NFORMATIC	ON DISC	CLOSURE	Filing Date	February 27, 2004	
S	TATEMEN	T BY AP	PLICANT	First Named Inventor	Chien-Hsuan HAN	
				Art Unit	1615	
	(use as many sheets as necessary)			Examiner Name	H. SHEIKH	
Sheet	1	of	3	Attorney Docket Number	49393-00004	

			U.S. PATE	NT DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

	FOREIGN PATENT DOCUMENTS									
		Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines,					
Examiner Initials*	Cite No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁵				

Applicant's unique citation designation number (optional). ³ See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials	No.1 item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number publisher, city and/or country where published.			
/SM/	B1	ATTWELL, ET AL., "EFFECT OF CARBIDOPA DOSE ON PHARMACOKINETIC AND METABOLIC HANDLING OF AN ORAL BOLUS OF L-DOPA IN RATS," BRITISH JOURNAL OF PHARMACOLOGY (1990), 101:496P.		
/SM/	B2	BENABOU, ET AL., "HEPATOTOXIC PROFILE OF CATECHOL-O-METHYLTRANFERASE INHIBITORS IN PARKINSON'S DISEASE," EXPERT OPIN. DRUG SAF. (2003), 2(3): 263-267.		
/SM/	В3	BERGSTROM, ET AL., "CATECHOL-O-METHYLTRANSFERASE INHIBITION INCREASES THE UPTAKE OF 11C-3-(3,4-DIHYDROXYPHENYL)-L-ALANINE IN THE RAT PANCREAS," SCANDINAVIAN JOURNAL OF GASTROENTEROLOGY (1996), 31(12): 1216-1222.		
/SM/	B4	Bredberg, et al., "Pharmacokinetics of Levodopa and Carbidopa in Rats Following Different Routes of Administration," Pharmaceutical Research (1994), 11(4): 549-555.		
/SM/	B 5	FODALE, ET AL., "DRUGS OF ANESTHESIA, CENTRAL NICOTINIC RECEPTORS AND PARKINSON'S DISEASE," PARKINSONISM AND RELATED DISORDERS (2004), 10: 189-190.		
/SM/	B6	FORSBERG, ET AL., "PHARMACOKINETICS AND PHARMACODYNAMICS OF ENTACAPONE AND TOLCAPONE AFTER ACUTE AND REPEATED ADMINISTRATION: A COMPARATIVE STUDY IN THE RAT," THE JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS (2003), 304(2): 498-506.		
/SM/	В7	HENCHCLIFFE, ET AL., "ENTACAPONE IN THE MANAGEMENT OF PARKINSON'S DISEASE," EXPERT OPIN. PHARMACOTHER. (2002), 3(7): 957-963.		
/SM/	B8	ICHIKAWA, ET AL., "PHARMACOLOGICAL EFFECTS OF CABERGOLINE AGAINST PARKINSONISM," FOLIA PHARMACOL. JAPAN (2001), 117: 395-400.	7	
/SM/	B9	KARABAN, ET AL., "THE USE OF AMANTADINE SULFATE IN COMBINED THERAPY OF PARKINSON'S DISEASE," ZH NEVROL PSIKHIATR IM S S KORSAKOVA (2002), 102(7): 20-4.	7	

Examiner	/Snigdha Maewall/	Date	05/09/2007
Signature	, orngana maonan	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

to a collection of Information unless it contains a valid OMB control number.

Sut	bstitute for form 1449A/PTO	,		Complete if Known		
				Application Number	10/787,417	
11	NFORMATION	4 DI	SCLOSURE	Filing Date	February 27, 2004	
. 5	STATEMENT E	BY /	APPLICANT	First Named Inventor	Chien-Hsuan HAN	
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			Art Unit	1615	
l	(use as many she	eets as	necessary)	Examiner Name	H. SHEIKH	
Sheet	2	of	3	Attorney Docket Number	49393-00004	

	U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date Name of Patentee or Applicant of Cited Document		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	τ¢	
						\vdash	

Applicant's unique citation designation number (optional). ³ See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English (anguage Translation is attached.

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Cite No.1						
/SM/	B10	KULISEVSKY, ET AL., "ENTACAPONE: IS IT USEFUL AS COMPLEMENTARY TREATMENT WITH LEVODOPA?" REV. NEUROL. (1999), 28(8): 817-834.	1			
/SM/	B11	KUPSCH, ET AL., "LEVODOPA THERAPY WITH ENTACAPONE IN DAILY CLINICAL PRACTICE: RESULTS OF A POST-MARKETING SURVEILLANCE STUDY," CURRENT MEDICAL RESEARCH AND OPINION (2004), 20(1): 115-120.				
/SM/	B12	LEES, ET AL., "SUBLINGUAL APOMORPHINE AND PARKINSON'S DISEASE," JOURNAL OF NEUROLOGY, NEUROSURGERY, AND PSYCHIATRY (1989), 52(12): 1440.				
/SM/	B13	LOPEZ LOZANO, ET AL., "PREPARATION OF A LEVODOPA/CARBIDOPA SOLUTION IN ASCORBIC ACID (CITRIDOPA) AND CHROMATOGRAPHIC AND ELECTROCHEMICAL ASSESSMENT OF ITS STABILITY OVER 24 HOURS," NEUROLOGIA (APRIL, 1995), 10(4): 155-158.	√			
/SM/	B14	MONTASTRUC, ET AL., "BROMOCRIPTINE VERSUS LEVODOPA IN THE EARLY TREATMENT OF PARKINSON'S DISEASE. 1 ST RESULTS AFTER 2 YEARS," THERAPIE (OCT-DEC 1988), 43(6): 461-3.	1			
/SM/	B15	MONTASTRUC, ET AL., "COMPARISON OF BROMOCRIPTINE AND LEVODOPA AS FIRST LINE TREATMENT OF PARKINSON'S DISEASE: RESULTS OF A 3-YEAR PROSPECTIVE RANDOMIZED STUDY," REV. NEUROL. (PARIS) (1990), 146(2): 144-7.	1			
/SM/	B16	MONTASTRUC, ET AL., "A PILOT STUDY OF N-METHYL-D-ASPARTATE (NMDA) ANTAGONIST IN PARKINSON'S DISEASE," JOURNAL OF NEUROLOGY, NEUROSURGERY, AND PSYCHIATRY (1992), 55(7): 630-631.				
/SM/	B17	RASCOL, "DATA IN FAVOR OF DOPAMINERGIC AGONISTS ONLY," REV. NEUROL. (PARIS) (1999), 155(1): 35-42.	7			
/SM/	B18	REICHMANN, ET AL., "PRAMIPEXOL BEI DER PARKINSON-KRANKHEIT: ERGEBNISSE EINER ANWENDUNGSBEOBACHTUNG," DER NERVENARZT (AUGUST 2002), 73: 745-750.	1			

				_
Examiner	/Cmindha Maassall/	Date	05/09/2007	1
Signature	/Snigdha Maewall/	Considered	00/00/2001	ı

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached.

Sut	stitute for form 1449A/PTO			Complete if Known			
02.				Application Number	10/787,417		
11	VFORMATION	1 DI	SCLOSURE	Filing Date	February 27, 2004		
5	STATEMENT I	BY /	APPLICANT	First Named Inventor	Chien-Hsuan HAN		
				Art Unit	1615		
	(use as many sh	eets as	necessary)	Examiner Name	H. SHEIKH		
Sheet	3	of	3	Attorney Docket Number	49393-00004		

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	

	FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	τ⁰	

Applicant's unique citation designation number (optional). ³ See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initlets	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/SM/	B19	ROSE, ET AL., "THE EFFECT OF CARBIDOPA ON THE PHARMACOKINETICS OF L-DIHYDROXYPHENYLALANINE IN THE RAT," EUROPEAN JOURNAL OF PHARMACOLOGY (1990), 183(3): 968-969.	
/SM/	B20	SANTENS, "SLEEP ATTACKS IN PARKINSON'S DISEASE INDUCED BY ENTACAPONE, A COMT-INHIBITOR," FUNDAMENTAL & CLINICAL PHARMACOLOGY (2003), 17: 121-123.	
/SM/	B21	SHUTO, ET AL., "(1S,2R)-1-PHENYL-2-[(S)-1-AMINOPROPYL]-N, N-DIETHYLCYCLOPROPANE-CARBOXAMIDE (PPDC), A NEW CLASS OF NMDA-RECEPTOR ANTAGONIST: MOLECULAR DESIGN BY A NOVEL CONFORMATIONAL RESTRICTION STRATEGY," JPN. J. PHARMACOL. (2001), 85: 207-213.	
/SM/	B22	SMITH, ET AL., "IN VITRO METABOLISM OF TOLCAPONE TO REACTIVE INTERMEDIATES: RELEVANCE TO TOLCAPONE LIVER TOXICITY," CHEM. RES. TOXICOL. (2003), 16(2): 123-128.	
/SM/	B23	WIKBERG, ET AL., "IDENTIFICATION OF MAJOR URINARY METABOLITES OF THE CATECHOL-O- METHYLTRANSFERASE INHIBITOR ENTACAPONE IN THE DOG," EUROPEAN JOURNAL OF DRUG METABOLISM AND PHARMACOKINETICS (1993), 18(4): 359-367.	
/SM/	B24	"DA AGONISTS - NON-ERGOT DERIVATIVES: PRAMIPEXOLE," MOVEMENT DISORDERS (2002), 17(SUPP 4): S93-S97.	
/SM/	B25	CARBIDOPA AND LEVODOPA TABLETS, PRODUCT INSERT, SEPTEMBER 2001.	
/SM/	B26	CARBIDOPA, OFFICIAL MONOGRAPHS, U.S. PHARMACOPEIA 26, PP. 328-329.	
/SM/	B27	LODOSYN ® (CARBIDOPA) TABLETS, PHYSICIANS' DESK REFERENCE, 57 ¹¹ EDITION (2003), PP. 1090-1092.	

Examiner	/Snigdha Maewall/	Date	05/09/2007
Signature	/Snigana iviaewaii/	Considered	00/00/2001

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached.